IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

ANASTASIA JOHNSTON, *et al.*,

Plaintiffs,

-vs-

MYLAN SPECIALTY L.P.,

Defendant.

Case No. 2:16-CV-13060-GAD-SDD

Hon. Gershwin Drain

DEFENDANT MYLAN SPECIALTY L.P.'S MOTION TO DISMISS

Defendant Mylan Specialty L.P. ("Defendant" or "Mylan"), through its counsel Clark Hill PLC and Hogan Lovells US LLP and pursuant to Federal Rule of Civil Procedure 12(b)(6), moves for entry of an order dismissing Plaintiffs' Complaint with prejudice, for failure to state a claim upon which relief can be granted. In the alternative, Defendant moves to strike the class allegations in Plaintiffs' Complaint pursuant to Federal Rule of Civil Procedure 12(f). In support of this Motion, Defendant relies on the attached brief in support.

In accordance with Local Rule 7.1(a), on November 21, 2016, concurrence was sought but not received.

Respectfully submitted,

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Dated: November 22, 2016

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DEFENDANT MYLAN SPECIALTY L.P.'S
BRIEF IN SUPPORT OF ITS MOTION TO DISMISS

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ISSUES PRESENTED

1. Whether this Court should grant Mylan's Motion pursuant to Fed. R. Civ. P. 12(b)(6), where Plaintiffs have failed to state any claim upon which relief can be granted as: (1) Plaintiffs do not have standing to bring a claim, (2) Plaintiffs have not pled the requirements to bring an action under state consumer protection law, (3) Plaintiffs have not pled the requirements for unjust enrichment, and (4) Plaintiffs' claims are preempted by federal patent law?

2. In the alternative, whether this Court should strike Plaintiffs' class allegations, where Plaintiffs' proposed class would be governed by the laws of fifty states and where individualized inquiries would be necessary to determine causation?

CONTROLLING AUTHORITY

Biotech. Indus. Org. v. Dist. of Columbia, 496 F.3d 1362 (Fed. Cir. 2007)

Corder v. Ford Motor Co., 869 F. Supp. 2d 835 (W.D. Ky. 2012)

Gen. Insulation Co. v. Eckman Constr., 992 A.2d 613 (N.H. 2010)

George v. Al Hoyt & Sons, Inc., 27 A.3d 697 (N.H. 2011)

In re Auto. Parts Antitrust Litig., No. 12-md-02311, 2013 WL 2456612 (E.D. Mich. June 6, 2013)

In re Packaged Ice Antitrust Litig., 779 F. Supp. 2d 642 (E.D. Mich. 2011)

Kentucky v. Marathon Petroleum Co., LP, CIV.A. No. 3:15-cv-354-DJH, 2016 WL 3199534 (W.D. Ky. June 8, 2016)

Kussy v. Home Depot U.S.A., Inc., Case No. 06-12899, 2006 WL 3447146 (E.D. Mich. Nov. 28, 2006)

L'Esperance v. HSBC Consumer Lending, Inc., 2012 DNH 104 (D.N.H. 2012)

Mayhall v. A.H. Pond Co., Inc., 341 N.W.2d 268 (Mich. App. 1983)

Pilgrim v. Univ. Health Card, LLC, 660 F.3d 943 (6th Cir. 2011)

Skilcraft Sheetmetal, Inc. v. Ky. Mach., Inc., 836 S.W.2d 907 (Ky. Ct. App. 1992)

Southeastern Pa. Transp. Auth. v. Gilead Sciences, Inc.,102 F. Supp. 3d 688 (E.D. Pa. 2015)

Spokeo, Inc. v. Robins, 136 S. Ct. 1540 (2016)

Stevenson Lumber Co.-Suffield, Inc. v. Chase Assocs., Inc., 932 A.2d 401 (Conn. 2007)

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INTRODUCTION

This is a case about Plaintiffs' inappropriate efforts to capitalize on recent controversies surrounding the list price of the EpiPen® ("EpiPen") Auto-Injector by substituting their personal views for the judgment of top medical professionals. Plaintiffs allege that Defendant Mylan Specialty L.P. ("Mylan" or "Defendant") made misrepresentations regarding the potential need for more than one EpiPen device in the event of a severe allergy attack and improperly sold its EpiPen products in packages of two in order to charge inflated prices. On this basis, they allege state consumer protection and unjust enrichment claims on behalf of a putative class.

Plaintiffs' claims are wanting in several respects, starting with the fact that Mylan's decision to sell EpiPen devices in two-packs is consistent with the recommendation of the lead institute for research on food allergies at the National Institutes of Health, as well as a leading international allergy organization. Selling the EpiPen Auto-Injector in two-packs can save lives, and it would be a perverse result indeed if Plaintiffs could use state consumer protection laws to endanger consumer health and safety in the name of a class action lawsuit.

Plaintiffs' Complaint is deficient as a matter of law and should be dismissed. Plaintiffs cannot bring a claim based on the number of items that Mylan chooses to put in its package, because, standing alone, a product manufacturer has the right to put as few or as many products in a package as it wants. Plaintiffs thus try to concoct a lawsuit based on the notion that Mylan somehow "misled" consumers about the benefits of carrying two EpiPen devices rather than one. But Plaintiffs

do not have standing to pursue such a lawsuit because they have not suffered any injury-in-fact that is fairly traceable to Mylan.

More to the point, Plaintiffs' claims are inherently speculative. One cannot know whether Plaintiffs will ever need to use an EpiPen device, or even two. EpiPen devices are emergency-use products that people carry with the hope of never needing to use them. And to be sure, the majority of EpiPen device purchasers will never need to use them. Does that mean the putative class has been deceived or defrauded? No, because some people *will* need them, and there is no way to know in advance who will suffer that life-threatening allergic reaction. The same principle applies to the second dose of epinephrine. Most purchasers will never need it, but some will, and there is no way to know in advance who that will be. Mylan made a decision to ensure that all patients prescribed an EpiPen device will be prepared for that event. The fact that Plaintiffs never needed two doses of epinephrine to save a life does not mean they have suffered any "injury" within the meaning of Article III.

Moreover, for a number of reasons, Plaintiffs' consumer protection and unjust enrichment claims all fail as pled, and to the extent Plaintiffs seek to use state law to regulate the price of patented EpiPen devices, their claims are preempted by federal patent law. There is another problem too: the claims that Plaintiffs assert are inherently incapable of being brought as a class action. Accordingly, the Court should dismiss the Complaint with prejudice in its entirety, or alternatively, strike Plaintiffs' class allegations because the requirements for maintaining a class action cannot be met.

BACKGROUND[1]

Epinephrine is a life-saving drug "used for emergency treatment of severe allergic reactions (including anaphylaxis) caused by insect bites or stings, medicines, foods, or other substances." Compl. ¶ 13. An EpiPen device is "a type of epinephrine injection device, or autoinjector," that simplifies the process of delivering epinephrine to the body. *Id.* ¶ 15. EpiPen products allow a patient to quickly and safely self-administer the prescribed amount of epinephrine through a spring-loaded needle. *Id.* Defendant Mylan Specialty L.P., formerly known as Dey Pharma, L.P., has held worldwide, exclusive rights to patented EpiPen auto-injector technology since 2007.[2] *Id.* ¶¶ 9, 18, 19.

In December 2010, the National Institute of Allergy and Infectious Diseases ("NIAID") published its *Guidelines for the Diagnosis and Management of Food Allergy in the United States* (the "NIAID Guidelines"), attached hereto as **Exhibit A**.[3] *Id.* ¶ 22. The NIAID, which is the lead institute for research on food allergy at

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[1] Mylan denies the allegations in Plaintiffs' Complaint, but unless otherwise noted, assumes the truth of those allegations solely for purposes of moving to dismiss under Rule 12(b)(6).

[2] The patents on the EpiPen Auto-Injector device include U.S. Patent numbers 7,449,012; 7,794,432; 8,048,035; and 8,870,827, of which the court may take judicial notice. *See Anderson v. Kimberly-Clark Corp.*, 570 F. App'x 927, 932 (Fed. Cir. 2014). Meridian Medical Technologies, Inc. ("Meridian") owns the patents related to EpiPen devices, and has granted Mylan Specialty L.P. the exclusive rights to market, distribute, and sell EpiPen products.

[3] This document is publicly available at https://www.niaid.nih.gov/diseases-conditions/guidelines-clinicians-and-patients-food-allergy. The Court may properly consider the NIAID Guidelines in relation to Mylan's Rule 12(b)(6) motion, because they are referenced in and integral to the allegations of the

the National Institutes of Health, developed the Guidelines "over a 2-year period through the combined efforts of an Expert Panel and Coordinating Committee representing 34 professional organizations, federal agencies, and patient advocacy groups." Ex. A at S4. "The Expert Panel drafted the Guidelines using an independent, systematic literature review and evidence report on the state of science in food allergy, as well as their expert clinical opinion." *Id.*

The NIAID Guidelines state that some patients suffering from anaphylaxis require a second dose of epinephrine before experiencing relief, and therefore recommend that patients receive a prescription for two epinephrine auto-injectors. In particular, the NIAID Guidelines state as follows:

- "Epinephrine has an onset of action within minutes but is rapidly metabolized. Therefore, the effect is often short-lived and ***repeated doses may be necessary***. If a patient responds poorly to the initial dose or has ongoing or progressive symptoms despite initial dosing, ***repeated dosing may be required after 5 to 15 minutes.*** Reports of patients receiving epinephrine for food-induced or nonfood-induced anaphylaxis note that ***as high as 10% to 20% of individuals who receive epinephrine will require more than 1 dose before recovery of symptoms***." Ex. A § 6.3.1.1, p. S40 (emphasis added).

- "All patients who have experienced anaphylaxis should be sent home with the following: . . . Epinephrine auto-injector (***2 doses***)." *Id.* § 6.4.2, p. S42 (emphasis added).

- "Epinephrine auto-injector (or 2-dose prescription). All patients experiencing anaphylaxis should be provided directly with an epinephrine auto-injector or, if this is not possible, with a prescription

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Complaint. *See Ouwinga v. Benistar 419 Plan Servs., Inc.*, 694 F.3d 783, 796 (6th Cir. 2012). *See also* Compl. ¶¶ 22-29, 35.

(***recommended prescription is for 2 doses of epinephrine***), and advised to fill it immediately." *Id.* § 6.4.2.2, p. S42 (emphasis added).

In February 2011, the World Allergy Organization ("WAO") addressed epinephrine dosage in its *Guidelines for the Assessment and Management of Anaphylaxis* (the "WAO Guidelines"), a copy of which is attached as **Exhibit B**.[4] The WAO Guidelines state that up to 23 percent of adults receiving an epinephrine injection for anaphylaxis have required at least two doses, and recommend that physicians prescribe more than one epinephrine auto-injector per patient. The WAO Guidelines provide, in relevant part, as follows:

- "Depending on the severity of the episode and the response to the initial injection, the dose can be repeated every 5-15 minutes, as needed. Most patients respond to 1 or 2 doses of epinephrine injected intramuscularly promptly; however, more than 2 doses are occasionally required." Ex. B at 593.e9.

- "Basic Management of Anaphylaxis. Preliminary Steps. . . . 5) Inject epinephrine (adrenaline) intramuscularly in the mid anterolateral aspect of the thigh, 0.01 mg/kg of a 1:1,000 (1 mg/mL) solution, to a maximum of 0.5 mg (adult) or 0.3 mg (child); ***record the time of the dose and repeat it in 5-15 minutes, if needed; most patients respond to 1 or 2 doses.***" *Id.* at 593.e11, Table 5 (emphasis added).

- "[M]ore than one epinephrine injection is needed in up to 23% of adults receiving an epinephrine injection for anaphylaxis; therefore, ***consider prescribing more than one epinephrine auto-injector***." *Id.* at 593.e18, Table 9, n. (a) (emphasis added).

[4] This document is publicly available at http://www.worldallergy.org/anaphylaxis. The Court may properly consider the WAO Guidelines in relation to Mylan's Rule 12(b)(6) motion, because they are referenced in and integral to the allegations of the Complaint. *See Ouwinga*, *supra*. *See also* Compl. ¶ 26.

Consistent with the NIAID and WAO Guidelines, Mylan decided to repackage its EpiPen devices so that individuals at risk for anaphylaxis would have access to at least two doses of epinephrine in the event of a severe allergic reaction. On August 24, 2011, Mylan issued a press release titled, "Dey Pharma to Offer EpiPen 2-Pak® and EpiPen Jr 2-Pak® Exclusively" (the "Press Release"), a copy of which is attached as **Exhibit C**.[5] The Press Release announced that in accordance with the NIAID and WAO Guidelines, Mylan would begin offering EpiPen Auto-Injectors exclusively in packs of two. The Press Release, which contains citations to the NIAID and WAO Guidelines, states in relevant part as follows:

- "Dey Pharma, L.P., a subsidiary of Mylan Inc. (Nasdaq:MYL), today announced that Dey will exclusively offer the EpiPen 2-Pak® and EpiPen Jr 2-Pak® (epinephrine) Auto-Injector 0.3/0.15 mg, to encourage physicians and patients to follow recommendations by the National Institute of Allergy and Infectious Diseases (NIAID)." Ex. C at 1.

- "The 'Guidelines for the Diagnosis and Management of Food Allergy in the United States,' which were developed by an expert panel sponsored by the NIAID, a division of the National Institutes of Health (NIH), recommend that patients at risk for or who have experienced anaphylaxis have immediate access to two doses of epinephrine. More specifically, the guidelines indicate that if a patient responds poorly to the initial dose or has ongoing or progressive

[5] This document is publicly available at http://newsroom.mylan.com/press-releases?item=123046. The Court may properly consider the Press Release in relation to Mylan's Rule 12(b)(6) motion, because the Press Release is referenced in and integral to the allegations of the Complaint. *See Ouwinga*, 694 F.3d at 796. *See also* Compl. ¶ 22.

symptoms despite initial dosing, repeated dosing may be required after five to 15 minutes." *Id.*

- Mylan "commented: 'Many people may not be aware that recent food allergy guidelines state that patients at risk for or who have experienced anaphylaxis should have immediate access to two doses of epinephrine. The decision to exclusively offer the EpiPen 2-Pak, which contains two single EpiPen Auto-Injectors, aligns with these guidelines, as well as with the 2011 World Allergy Organization (WAO) anaphylaxis guidelines which recommend that physicians consider prescribing more than one epinephrine auto-injector.'" *Id.*

- "Dr. Phillip Lieberman, Clinical Professor of Medicine and Pediatrics at University of Tennessee College of Medicine, and member of the NIAID-sponsored expert panel added: 'The guidelines recognize that up to 20% of those who receive epinephrine will require more than one dose before symptoms are relieved. In addition, the need for additional epinephrine cannot be reliably predicted at the outset of a reaction. Therefore, consistent with the guidelines, patients prescribed an epinephrine auto-injector should be given a prescription which allows two doses.'" *Id.* at 2.

Plaintiffs claim Mylan "misstated the science regarding, and regulatory framework governing, EpiPens in order to require consumers to buy extra, unneeded EpiPens, which are likely to go to waste, at an inflated cost." Compl. ¶ 36. Plaintiffs further claim Mylan's decision to only sell EpiPen devices in packs of two, while using the NIAID report as "an excuse," has "misled the American public" and "forced purchases of additional EpiPens—which are wasteful to patients but a windfall for Defendants." *Id.* ¶¶ 33, 35. Plaintiffs allege that by issuing the Press Release and selling EpiPen devices only in packs of two, Mylan violated "the applicable Unfair Trade and Deceptive Practices Acts and/or Consumer Protection Acts of all States where Defendants do business," and

violated the laws of Michigan, Connecticut, Kentucky, and New Hampshire. Compl. ¶¶ 50-61, 63-67, 69-73, 74-79, 81-85, and 86-92.

STANDARD OF REVIEW

In order to survive a motion to dismiss, a complaint must contain "more than an unadorned, the-defendant-unlawfully-harmed-me accusation." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). "The purpose of a Rule 12(b)(6) motion to dismiss is to allow a defendant to test whether, as a matter of law, the plaintiff is entitled to legal relief even if everything alleged in the complaint is true." *Mayer v. Mylod*, 988 F.2d 635, 638 (6th Cir. 1993). Thus, "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements do not suffice." *Iqbal*, 556 U.S. at 678. Legal conclusions instead must be supported by factual allegations and the complaint must state a plausible claim for relief. *Id.* at 679. Those "[f]actual allegations must be enough to raise a right to relief above the speculative level." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). Here, Plaintiffs' Complaint fails these well-established standards and fails to state any claim under Michigan, Connecticut, New Hampshire, or Kentucky law.

ARGUMENT

Plaintiffs allege six counts in their Complaint: (1) violation of all states' deceptive and unfair trade practice acts and/or consumer protection acts, (2) violation of the Kentucky Consumer Protection Act, (3) violation of the Michigan Consumer Protection Act, (4) violation of the New Hampshire Consumer Protection Act, (5) violation of the Connecticut Consumer Protection Act, and (6) unjust enrichment. As shown below, Plaintiffs lack standing to assert these

claims, and all six counts fail as a matter of law. Moreover, even if some portion of the Complaint were to survive dismissal (and it should not), the Court should strike Plaintiffs' class allegations.

I. PLAINTIFFS LACK STANDING TO PURSUE THEIR CLAIMS.

"No principle is more fundamental to the judiciary's proper role in our system of government than the constitutional limitation of federal-court jurisdiction to actual cases or controversies," as defined in Article III. *Taylor v. KeyCorp*, 680 F.3d 609, 612 (6th Cir. 2012) (quoting *Simon v. E. Ky. Welfare Rights Org.*, 426 U.S. 26 (1976)). To establish Article III standing, a plaintiff must demonstrate three elements: (1) an injury-in-fact, (2) a sufficient causal connection between the injury and the conduct complained of, and (3) a likelihood that the injury will be redressed by a favorable decision. *Id.* at 612 (quoting *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992)).

As the party invoking federal jurisdiction, plaintiff has the burden of establishing each of these elements, and at the pleading stage, "the plaintiff must 'clearly . . . allege facts demonstrating' each element.'" *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 (2016) (quoting *Warth v. Seldin*, 422 U.S. 490, 518 (1975)). Plaintiffs have not met that burden in this case because they have not pled the first or second elements of standing. Therefore, Plaintiffs' Complaint should be dismissed pursuant to Fed. R. Civ. P. 12(b)(1).

A. Plaintiffs Have Not Pled an Injury-in-Fact.

Plaintiffs have not pled the "'[f]irst and foremost' of standing's three elements": injury in fact. *Spokeo*, 136 S. Ct. at 1547 (citation omitted). An

injury-in-fact is "an invasion of a legally protected interest which is (a) concrete and particularized, . . . and (b) 'actual and imminent,' not 'conjectural' or 'hypothetical.'" *Lujan*, 504 U.S. at 560 (citation omitted).

1. Plaintiffs Have Not Pled Facts to Support Any Injury.

As a threshold matter, Plaintiffs have not even *alleged* any injury. Plaintiffs' Complaint contains one sentence stating allegations actually relating to their personal experiences, which reads as follows: "Each of the Plaintiffs purchased a two pack of EpiPens for their own protection or that of a friend or family member." Compl. ¶ 37. That is all. Plaintiffs do not indicate whether they paid out of pocket or whether insurance covered some or all of the prescription, as is usually the case. Nor do they allege what prices they paid, or if they paid at all; whether or why or to what extent the price that they paid was too high; or how the mere "purchase" of an EpiPen Auto-Injector, standing alone, could result in an injury at all. Because Plaintiff have alleged no injuries to themselves, much less injuries that meet the requirements of Article III, their Complaint should be dismissed.

2. Plaintiffs Cannot Plead Any Facts that Would Support an Injury.

Even if Plaintiffs tried to allege standing, they could not, because the Complaint is premised only on "'conjectural' or 'hypothetical'" injury. *Lujan*, 504 U.S. at 560 (citation omitted). It is well-established that "Plaintiffs do not allege

an injury-in-fact when they rely on a 'chain of contingencies' or 'mere speculation.'" *Finkelman v. Nat'l Football League*, 810 F.3d 187, 193 (3d Cir. 2016) (citations omitted). Likewise, "[a]llegations of potential future injury, or the mere possibility of a future injury, will not establish standing." *Cottrell v. Alcon Labs., Inc.*, No. CV 14-5859(FLW), 2016 WL 1163163, at *3 (D.N.J. Mar. 24, 2016) (citing *Whitmore v. Arkansas,* 495 U.S. 149, 158 (1990)), a copy of which is attached as **Exhibit D**. That is one of the fatal flaws in Plaintiffs' allegations here.

Plaintiffs have alleged that they each purchased a two-pack of EpiPen devices, Compl. ¶ 37, but any injury from that purchase is, and will remain, purely conjectural. The thrust of the Complaint is that Mylan "require[s] consumers to buy extra, ***unneeded*** EpiPens, ***which are likely to go to waste***, at an inflated cost." *Id*. ¶ 36 (emphasis added). To allege an injury from the purchase of two EpiPen devices, rather than one, each Plaintiff thus would need to allege that she only needed one EpiPen device but was deceived into purchasing two. Such an allegation cannot truthfully be made. Unless and until each Plaintiff suffers a severe allergic reaction and uses the EpiPen products that she bought, it is pure conjecture whether she would need both devices in the package or only one. And even then, if any Plaintiff only used one of the two devices during an allergy attack (or none), she would not have suffered any "injury" from her purchase, because there would have been no way to know at the time of purchase how many EpiPen Auto-Injectors would be required. "[M]ore than one epinephrine injection is needed in up to 23% of adults receiving an epinephrine injection for anaphylaxis." Ex. B at 593.e18, Table 9, n. (a) (WAO Guidelines). *See also* Ex. A § 6.3.1.1, p.

S40 (NIAID Guidelines). Was each Plaintiff in that 23% at the time they made their purchases or not? Would they even suffer an allergy attack at all? How could this have been ascertained at time of purchase? There is no way to answer these questions, and thus no way to establish any injury-in-fact beyond one that improperly relies on a 'chain of contingencies' or 'mere speculation.'" *Finkelman*, 810 F.3d at 193 (citations omitted).

Consider, for example, a consumer who purchases car insurance but never has an accident during the policy period. The money spent on buying insurance could not possibly be an "injury," because it did exactly what it was supposed to do – it protected the consumer against possible harm that, fortunately, never occurred. To say otherwise at the time of purchase would be pure conjecture, because there is no way to know whether an accident would occur, much less whether the consumer was deceived into buying more insurance than they ended up needing. So too here. Individuals purchase EpiPen devices with the hope never to have an anaphylactic reaction, and therefore never to use an EpiPen device at all. At the time of purchase, Plaintiffs had no way to know whether they would need zero, one, two, or more EpiPen devices.

Plaintiffs thus cannot suffer a cognizable injury based on the purchase of two EpiPen Auto-Injectors. A consumer cannot be "injured" by buying two EpiPen devices as insurance against an allergy attack any more than they could be "injured" by buying car insurance. Plaintiffs are asserting claims based entirely on hypothetical scenarios that are impossible to know, and which are therefore insufficient to establish standing. *Young v. Johnson & Johnson*, CIV.A. No. 11-

4580 JAP, 2012 WL 1372286, at *3 (D.N.J. Apr. 19, 2012), *aff'd*, 525 F. App'x 179 (3d Cir. 2013) (dismissing claim where alleged injury was based on speculation and fear of future harm; "apprehension about a possible future injury is insufficient to establish injury-in-fact"), a copy of which is attached as **Exhibit E**. *See also Cottrell*, 2016 WL 1163163, at *7; *Finkelman*, 810 F.3d at 200.[6]

B. Plaintiffs Have Not Pled That Mylan Caused Their Injuries.

Plaintiffs also have not pled a "causal connection between the injury and the conduct complained of." *Cottrell*, 2016 WL 1163163, at *3. It is black-letter law that an alleged injury "has to be fairly traceable to the challenged action of the defendant, and not the result of the independent action of some third party not before the court." *Id*. (citing *Lujan*, 504 U.S. at 560-61). The requirement is "akin to but-for causation in tort." *Finkelman*, 810 F.3d at 193.

Here, Mylan's decision to sell EpiPen devices in packages of two rather than one, and the issuance of a Press Release explaining that decision, does not – and cannot – cause anyone harm, even indirectly. If Plaintiffs did not use both EpiPen devices in each package, that would be the result of independent factors that had

[6] It is not enough for Plaintiffs to allege that there is "minimal evidence" showing that a second dose of epinephrine is needed for patient safety. Compl. ¶ 31. The Complaint admits that some percentage of individuals need a second dose of epinephrine, and that, at least in certain cases, there may not be time for a second dose to be administered by a physician. *Id*. That concession destroys any argument for standing. This is not a case where a consumer is deceived into buying boat insurance when they do not own a boat; it is a claim about having bought more insurance for their car than they need – i.e., buying one more EpiPen device than may ultimately be required. That fact is unknowable at the time of purchase and thus cannot give rise to an injury under Article III.

nothing to do with Mylan's decision to package the product in a certain way, much less the statements in the Press Release on which Plaintiffs rely. It instead would be the result of Plaintiffs being fortunate enough not to have suffered an allergic reaction that caused them to need both of the EpiPen devices that they purchased.

Indeed, the alleged injury – unused EpiPen devices – is not from the *purchase* of a two-pack of EpiPen devices or Mylan's decision to sell EpiPen devices in two-packs. Instead, as Plaintiffs allege, it is from whether there was a *need* for those EpiPen devices. *See, e.g.*, Compl. ¶¶ 31. And that, in turn, is due to "independent actions," such as the severity of the person's medical reaction, the allergen to which they are exposed, whether a third party served them food when told not to, or even whether they happened to get stung by an insect that triggered a more severe attack. Hopefully, Plaintiffs are lucky enough not to need any of their EpiPen devices, but regardless, whether they do or not cannot "be fairly traceable to the challenged action" in this Complaint. *Cottrell*, 2016 WL 1163163, at *3.

II. PLAINTIFFS FAIL TO STATE A CLAIM UNDER STATE CONSUMER PROTECTION LAW.

Plaintiffs' first count alleges that Mylan violated the "applicable Unfair Trade and Deceptive Practices Acts and/or Consumer Protection Acts of all States where Defendants do business." Compl. ¶ 58. However, Plaintiffs do not have standing to assert such a claim because they have not alleged that they reside in or have been injured in all of these states. *In re Packaged Ice Antitrust Litig.*, 779 F. Supp. 2d 642, 653-59 (E.D. Mich. 2011) (holding that named plaintiffs lacked standing to bring claims under the laws of states other than their home states).

When no named plaintiff has standing to assert a particular claim, that claim fails. *Id.* at 659 (dismissing for lack of standing all claims asserted under the laws of states in which no plaintiff resided or suffered injury). Therefore, Plaintiffs' catch-all claim under the consumer protection laws of all states where Mylan does business should be dismissed.

With respect to the consumer protection laws of states in which Plaintiffs reside, Plaintiffs still fail to state a claim. Plaintiffs fail to allege that Mylan made any misrepresentations that could form the basis of a claim under Michigan or Connecticut consumer protection law. Plaintiffs also fail to allege conduct that meets the requirements for stating a claim under the New Hampshire or Kentucky consumer protection statutes. In addition, Plaintiffs do not plead causation, as required by the consumer protection laws of every state in which Plaintiffs reside.

A. Plaintiffs Fail to Allege a Misrepresentation that Could Give Rise to a Claim Under Michigan or Connecticut Consumer Protection Law.

Plaintiffs fail to state that Mylan actually made any misleading or deceptive statements, as required to state a claim under the Michigan Consumer Protection Act or the Connecticut Unfair Trade Practices Act. Pursuant to the Michigan Consumer Protection Act ("MCPA"), Mich. Comp. Laws Ann. § 445.903(1), "[u]nfair, unconscionable, or deceptive methods, acts, or practices in the conduct of trade or commerce are unlawful . . . ." The MCPA expressly defines and enumerates "unfair, unconscionable, or deceptive methods, acts, or practices" in 35 distinct subsections. The majority of the subsections address misrepresentations or

omissions of information and, therefore, "it is proper to construe the provisions of the MCPA with reference to the common law tort of fraud." *Zine v. Chrysler*, 600 N.W. 2d 384 (Mich. App. 1999) (internal quotations and citation omitted). A plaintiff claiming violation of the MCPA generally must show: "1) that the defendant made a material misrepresentation that was false; 2) the defendant knowingly made the false representation with the intent that the plaintiff would act upon it; 3) that the plaintiff acted in reliance upon it; and 4) resulting damages."[7] *Kussy v. Home Depot U.S.A., Inc.*, Case No. 06-12899, 2006 WL 3447146, at *5 (E.D. Mich., Nov. 28, 2006) (citing *Baker v. Arbor Drugs, Inc.*, 544 N.W.2d 727 (Mich. App. 1996)), a copy of which is attached as **Exhibit F**. Additionally, a plaintiff alleging violation of the MCPA must meet the heightened pleading standard of Federal Rule of Civil Procedure 9(b). *Rosipko v. FCA US, LLC*, No. 15-11030, 2015 WL 8007649, at *4-5 (E.D. Mich., Dec. 7, 2015), a copy of which is attached as **Exhibit G**.

Plaintiffs' claim under the Connecticut Unfair Trade Practices Act ("CUTPA") also requires a misrepresentation. The CUTPA provides that "[n]o person shall engage in unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce." Conn. Gen. Stat. § 42-110b(a). Thus, Plaintiffs must plead that Mylan engaged in either "unfair" or

[7] In a class action, the named plaintiff must still allege and prove individual reliance on the subject representation. *Dix v. Am. Bankers Life Assurance Co. of Fl.*, 429 Mich. 410, 418; 415 N.W.2d 206 (1987).

"deceptive" acts.[8] Here, Plaintiffs allege that Mylan "violated [consumer protection] statutes by falsely representing that two doses of EpiPens were required in order to purportedly justify the Double Pack requirement and attendant price increase," and that Mylan's "concealment of material facts, including the effectiveness of single EpiPen[] doses and the actual reason for the two pack requirement, constitutes unconscionable commercial practices [and] deception." Compl. ¶¶ 56-57. In other words, the allegedly unconscionable or unfair behavior, according to Plaintiffs, was that Mylan "deceived" consumers by making misrepresentations regarding the safety benefits of selling EpiPen devices in two-packs. Therefore, to demonstrate that Mylan engaged in a deceptive or unfair act under the CUTPA, Plaintiffs likewise must plead that Mylan made an actionable misrepresentation.

Plaintiffs, however, fail to plead that Mylan made *any* deceptive misrepresentation that could give rise to a claim under the MCPA or the CUTPA. The sole basis for Plaintiffs' claim is that the Press Release allegedly misled consumers about the benefits of packaging EpiPen devices in packages of two.[9]

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[8] In determining whether a practice is "unfair" under CUTPA, a court will consider three factors: (1) whether the practice offends public policy as it has been established by statutes, the common law, or otherwise; (2) whether it is immoral, unethical, oppressive, or unscrupulous; or (3) whether it causes substantial injury to consumers. *Willow Springs Condo. Ass'n, Inc. v. Seventh BRT Dev. Corp.*, 245 Conn. 1, 43, 737 A.2d 77, 100 (Conn. 1998).

[9] Plaintiffs allege that Mylan "engaged in unconscionable, unfair, and/or deceptive acts by requiring consumers to buy the EpiPens as two packs." Compl. ¶ 52. However, a claim arising under the MCPA or the CUTPA must allege a

Yet the Press Release does nothing of the sort. To the contrary, it states that Mylan's decision to package EpiPen devices in sets of two aligned with the NIAID and WAO Guidelines – which is completely accurate. See Ex. C.

Attached as **Exhibit H** is a comparison of every relevant statement in the Press Release with the related statement in the Guidelines. As is clear from this Exhibit, the Press Release simply does not contain any deceptive or materially misleading statements. For example, the Press Release states that in up to approximately twenty percent of patients experiencing anaphylaxis, repeat dosing of epinephrine may be necessary every five to fifteen minutes. Ex. C at 1. That is exactly what the Guidelines say. *See* Ex. A §§ 6.3.1, 6.3.1.1, Table VI; Ex. B at 22, 23, 38, 30. Similarly, the Press Release relies on a recommendation that patients "have immediate access to two doses of epinephrine." Ex. C at 1. Again, that is what the Guidelines say: the NIAID guidelines expressly recommend that a patient who has experienced anaphylaxis should be prescribed two doses of epinephrine. *See* Ex. A §§ 6.4.2. And the same is true of every other statement in the Press Release as well. *See* Ex. D.

Further, to the extent Plaintiffs might argue that they rely on some statement or omission not specifically alleged in the Complaint, Plaintiffs' claim fails to meet the heightened pleading standard of Rule 9(b), which applies to deception-based claims. *See Rosipko, supra; Iqbal*, 556 U.S. at 678-79. Plaintiffs therefore point to

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misrepresentation or a deceptive act. The only deceptive statements Plaintiffs have alleged are in the Press Release.

no material misrepresentations that could give rise to a violation of the MCPA or the CUTPA.

B. Plaintiffs Do Not Plead Conduct Sufficient to Allege a Claim Under the New Hampshire Consumer Protection Act.

Plaintiffs also do not plead factual allegations that support a claim under the New Hampshire Consumer Protection Act ("NHCPA"). The NHCPA prohibits "an unfair method of competition or any unfair or deceptive act or practice in the conduct of any trade or commerce within this state." RSA § 358-A. The NHCPA then enumerates a non-exclusive list of sixteen acts that constitute "unfair method[s] of competition" or unfair or deceptive conduct. *Id*. When a complaint fails to identify an enumerated provision of RSA § 358-A:2, the court may presume the claim is made under the catch-all provision: "conduct 'of the same type as that proscribed in the enumerated categories' may also qualify as unfair or deceptive." *Galvin v. EMC Mortg. Corp.*, 2014 DNH 192, 29 (D.N.H. 2014) (citation omitted).

"In determining which commercial actions not specifically delineated are covered by the act, [New Hampshire has] employed the rascality test. Under the rascality test, the objectionable conduct must attain a level of rascality that would raise an eyebrow of someone inured to the rough and tumble of the world of commerce." *George v. Al Hoyt & Sons, Inc.*, 27 A.3d 697, 705 (N.H. 2011) (internal quotations and citations omitted).

Courts have found no NHCPA violation where a plaintiff understood and was not deceived by the terms of an agreement. *L'Esperance v. HSBC Consumer*

Lending, Inc., 2012 DNH 104 (D.N.H. 2012) (finding that "selling overpriced loans" did not rise to the level of "rascality" and did not give rise to a NHCPA claim where the costs and qualities of the products were plainly stated in the loan agreements, and where defendants did not have "superior knowledge" compared to plaintiffs); *see also Drew v. MAK Inv., LLC (In re Drew)*, 2006 BNH 29 (B.N.H. 2006) (plaintiff having signed a clear agreement, understanding its terms, was not deceived about the ultimate terms of the deal).

Here, Plaintiffs allege no specific violation of an enumerated act, and none is immediately applicable to this case. Therefore, in order to state a claim under the NHCPA, Plaintiffs must plead conduct rising to the level of "rascality" in order to make a claim under the catch-all provision of the NHCPA, which they have failed to do. First, all essential elements of the transaction were disclosed and known at the time of the purchases alleged in Plaintiffs' Complaint: the price paid by the consumer, the quantity, and the qualities of the product. Second, Plaintiffs cannot maintain an NHCPA claim based on allegations that Mylan sold overpriced drugs when the cost to the consumer was known and plainly stated at the time of sale. *L'Esperance*, 2012 DNH 104 at *63. Third, Plaintiff cannot allege that Mylan had superior knowledge of the information contained within the Guidelines, as these documents were and remain publicly available. *Id*. at *66. Fourth, Mylan's Press Release accurately represented the NIAID and WAO Guidelines. *See supra Section* II.A; Ex. D. Therefore, Plaintiffs fail to state a claim under the NHCPA.

C. Plaintiffs' Kentucky Consumer Protection Act Claim Fails Because Plaintiffs Do Not Allege Privity of Contract Between Mylan and Plaintiffs.

Plaintiffs' claim under the Kentucky Consumer Protection Act ("KCPA") is also fatally flawed. Kentucky courts require that privity of contract exist between parties in a suit alleging violation of the KCPA. *Skilcraft Sheetmetal, Inc. v. Ky. Mach., Inc.*, 836 S.W.2d 907, 909 (Ky. Ct. App. 1992) ("[A] subsequent purchaser may not maintain an action against a seller with whom he did not deal or who made no warranty for the benefit of the subsequent purchaser. The language of the statute plainly contemplates an action by a purchaser against his *immediate seller*.") (emphasis added)). *Skilcraft* distinguished cases where privity was not required by explaining that in those situations the defendant had provided warranties to the ultimate purchaser. *Id.* at 909 (citing *Ford Motor Co. v. Mayes*, 575 S.W.2d 480 (Ky. Ct. App. 1978)). *See also Naiser v. Unilever U.S., Inc.*, 975 F. Supp. 2d 727, 743 (W.D. Ky. 2013) ("[A] subsequent purchaser [can] not 'maintain an action against a seller with whom he did not deal or who made no warranty for the benefit of the subsequent purchaser.'") (citation omitted).

Here, Plaintiffs do not – and cannot – allege that they are in privity with Mylan. As Plaintiffs expressly acknowledge in their Complaint, epinephrine is available only by prescription (Compl. ¶ 13) and Mylan does not sell its EpiPen products directly to consumers. Rather, a consumer may only obtain an EpiPen device after receiving a prescription from his or her physician, having the prescription filled by a pharmacist, and then purchasing the EpiPen device from the pharmacist. Plaintiffs also do not allege that Mylan made any warranty for the

benefit of Plaintiffs. Therefore, as subsequent purchasers, Plaintiffs cannot state a claim under the KCPA.

D. Plaintiffs Do Not Plead Causation as Required to State a Consumer Protection Claim.

Even if Plaintiffs alleged a misrepresentation or other conduct that could give rise to a consumer protection claim, Plaintiffs do not – and cannot – allege their injuries were caused by the Press Release's statements. All four state consumer protection laws cited in the Complaint – Michigan,[10] Connecticut,[11] New Hampshire,[12] and Kentucky[13] – require proof of causation. Each requires a

[10] *Mayhall v. A.H. Pond Co., Inc.*, 129 Mich. App. 178, 183, 341 N.W.2d 268, 270 (1983) (under the MCPA, "in order to bring suit a plaintiff must suffer a 'loss' *as a result* of the statutory violation") (emphasis added).

[11] In *Stevenson Lumber*, the Connecticut Supreme Court stated that "in order to prevail in a CUTPA action, a plaintiff must establish both that the defendant has engaged in a prohibited act and that *as a result of this act*, the plaintiff suffered an injury." *Stevenson Lumber Co.-Suffield, Inc. v. Chase Associates, Inc.*, 284 Conn. 205, 214, 932 A.2d 401 (Conn. 2007) (emphasis added) (internal quotations and citation omitted). The court further explained that "[w]ith regard to the requisite causal element, it is axiomatic that proximate cause is [a]n actual cause that is a substantial factor in the resulting harm." *Id*. (internal quotation and citation omitted).

[12] *Mulligan v. Choice Mortg. Corp., USA*, No. CIV.A. 96-596-B, 1998 WL 544431, at *11 (D.N.H., Aug. 11, 1998) (for conduct to be actionable under the NHCPA, a plaintiff must establish a "*causal link* between the conduct at issue and his or her injury.") (emphasis added), a copy of which is attached as **Exhibit I**; *see also Lawrence v. Philip Morris USA, Inc.*, 53 A.3d 525, 530 (N.H. 2012) (reversing class certification where "*it would take individualized causation inquiries* to determine which putative class members saw such news reports prior to their purchase . . . . and understood the [product] to have [] problems.") (emphasis added) (internal quotations and citation omitted).

showing either that Plaintiffs' alleged injuries occurred "as a result of," or shared a "causal link" to, the alleged misstatements in the Press Release.

Here, Plaintiffs fail to allege that they ever saw the Press Release, let alone that the statements therein caused them to purchase EpiPen devices or to suffer any injury. Indeed, Plaintiffs never connect the Press Release or Mylan's alleged misrepresentations with their purchases of the EpiPen Auto-Injector in any way, and thus never allege that those misrepresentations *caused* them any harm. There could be (and likely were) myriad reasons why Plaintiffs purchased EpiPen products that have nothing to do with the Press Release or the purported misstatements on which Plaintiffs allegedly relied, including the most obvious source of information that would break any causal chain: what Plaintiffs were told by their doctors, which is conspicuously absent from the Complaint.

In fact, Plaintiffs have not even alleged with certainty that they would have taken the risk and purchased a single EpiPen device rather than two if that option had been available. The premise of Plaintiffs' claim requires a showing that they would have purchased EpiPen devices one at a time, but-for Mylan's "deceptive" acts that required them to purchase EpiPen two-packs instead. But that is not what the Complaint says. Instead, Plaintiffs assert in conclusory fashion that they

[13] *Corder v. Ford Motor Co.*, 869 F. Supp. 2d 835, 838 (W.D. Ky. 2012) (KCPA "requires only that the plaintiff prove that he or she suffered an 'ascertainable loss' that *was the 'result'* of the allegedly deceitful practice of the defendant," or in other words, a "causal nexus.") (emphasis added) (citation omitted); *see also Schlenk v. Ford Motor Credit Co.*, 308 F.3d 619, 622 (6th Cir. 2002) (KCPA claims were properly dismissed where plaintiff "failed to show any loss suffered *as a result* of" defendant's conduct) (emphasis added).

"would not have purchased the two packs" at all, "or only would have done so in light of the risk to their health from avoiding such purchase." Compl. ¶ 54. That just reinforces the point: because Plaintiffs admit they may have purchased a two-pack anyway "in light of the risk to their health," they have not alleged that Mylan's statements regarding the sale of EpiPen devices in packages of two rather than one were a but-for cause of their purchase decision. The Complaint does not allege that Plaintiffs actually saw any misrepresentations and relied on them, and asserts no causal link between Mylan's alleged conduct – issuing the Press Release and marketing EpiPen Auto-Injectors in packages of two – and any injury that Plaintiffs claim to have suffered. Plaintiffs thus fail to state a claim for violation of the Michigan, Connecticut, New Hampshire, and Kentucky Consumer Protection Acts.

III. PLAINTIFFS' STATE CONSUMER PROTECTION CLAIMS FAIL FOR ADDITIONAL REASONS.

A. Plaintiffs' Michigan Consumer Protection Act Claim is Barred by the Regulatory Exemption.

In addition to the deficiencies discussed above, Plaintiffs' MCPA claim also fails because Mylan is authorized to package, sell, and market EpiPen devices by the United States Food and Drug Administration ("FDA"). Section 445.904(1)(a) of the MCPA provides, "[t]his act does not apply to . . . (a) [a] transaction or conduct specifically authorized under laws administered by a regulatory board or officer acting under statutory authority of this state or the United States." The Michigan Supreme Court has held that, in determining if a transaction or conduct

is exempt from the scope of the MCPA, the relevant inquiry is "whether the general transaction is specifically authorized by law, regardless of whether the specific misconduct alleged is prohibited." *Smith v. Globe Life Ins. Co.*, 597 N.W.2d 28, 38 (Mich. 1999); *see also Molosky v. Wash. Mut., Inc.*, 664 F.3d 109, 117 (6th Cir. 2011) ("[A] general authorization is sufficient to exempt [a defendant] under [Section 445.904(1)(a)]". . . [and] the Supreme Court of Michigan explained the phrase to mean that the general transaction at issue, 'not the alleged misconduct,' must be mentioned specifically as authorized) (*quoting Liss v. Lewiston-Richards, Inc.*, 732 N.W.2d 514 (Mich. 2007)). For example, in *Alexander v. Del Monte Corp.*, plaintiffs alleged an MCPA claim based on injuries sustained while opening a jar of fruit. No. 09-12303, 2011 WL 87286, at *1 (E.D. Mich. Jan. 11, 2011), a copy of which is attached as **Exhibit J**. The court held that defendant Del Monte, which packaged the fruit, was exempt from the MCPA claim because it was specifically authorized by the FDA to engage in the packaging of food products. *Id.* at *3. The court also held that defendant Kroger, which sold the jar of fruit, was exempt from the MCPA claim because it was specifically authorized to sell food products by Michigan law. *Id.*

Applying this exemption to the marketing and sale of products approved by the FDA, courts uniformly hold that § 445.904(1)(a) applies to bar a claim for violation of the MCPA.[14] Here, Plaintiffs acknowledge that epinephrine is

[14] *See, e.g., Peter v. Stryker Orthopaedics, Inc.*, 581 F. Supp. 2d 813, 816 (E.D. Mich. 2008) (dismissing MCPA claim in connection with sale of prosthetic knee in part because medical devices are heavily regulated by the FDA); *Short v. Janssen Pharm., Inc.*, No. 1:14-CV-1025, 2015 WL 2201713, *5 (W.D. Mich. May 11,

available only by prescription and that EpiPen products are FDA-approved. Compl. ¶¶ 13, 16. Accordingly, because Mylan is authorized by the FDA to package, sell, and market EpiPen products, Plaintiffs' MCPA claim is barred by § 445.904(1)(a) and the Court should dismiss this count of Plaintiffs' Complaint.

B. Plaintiffs' Connecticut Unfair Trade Practices Act Claim is Barred by the Statute of Limitations.

Plaintiffs' CUTPA claim also suffers from an additional deficiency: the statute of limitations for such a claim has passed. Under § 42-110g(f), "[a]n action under this section may not be brought more than three years after the occurrence of a violation of this chapter." In *Fichera v. Mine Hill Corp.*, the Connecticut Supreme Court explained that the limitations period set forth by the Connecticut statute does *not* begin to run at the time of a plaintiff's injury or discovery of a violation. 207 Conn. 204, 212 (Conn. 1988). Instead, the limitations period begins to run upon the occurrence of the violation, "even where the wrongful act could not reasonably have been discovered until after the statute had run." *Id.* at 213. *See also Bellemare v. Wachovia Mortg. Corp.*, 94 Conn. App. 593, 606-07 (Conn. App. Ct. 2006) (holding that the three-year limitations period "applies to all claims brought under CUTPA without regard to the nature of the underlying unfair trade practice that has been alleged").

2015) (dismissing MCPA claim in connection with marketing of prescription drug where the FDA had not expressly authorized defendant's marketing practices), a copy of which is attached as **Exhibit K**.

Here, Plaintiffs allege misconduct that would have occurred in 2011, when Mylan issued the Press Release. Compl. ¶¶ 26-19, 31, 35. The limitations period for any claim arising out of statements made in the Press Release therefore expired in 2014 – two years before Plaintiffs brought this action. Conn. Gen. Stat. § 42-110g(f); *Fichera*, 207 Conn. at 212-13. Notably, Plaintiffs do not allege any fraudulent concealment that might have tolled the limitations period, nor can they – the Press Release and Guidelines are available publicly, and the Guidelines are cited in the Press Release. Accordingly, Plaintiffs' CUTPA claim is time-barred.

IV. PLAINTIFFS FAIL TO STATE A CLAIM FOR UNJUST ENRICHMENT.

Plaintiffs' sixth count is an equitable claim for unjust enrichment. Plaintiffs do not specify in their Complaint what law they seek to apply to this claim, which alone provides grounds for dismissal. *See In re Auto. Parts Antitrust Litig.*, No. 12-md-02311, 2013 WL 2456612, at *31 (E.D. Mich. June 6, 2013) (holding that defendants' "failure to identify the unjust enrichment laws of any particular jurisdiction subjects the causes of action to dismissal"), a copy of which is attached as **Exhibit L**. However, even if Plaintiffs had linked their unjust enrichment claims to the laws of the states in which Plaintiffs reside, their unjust enrichment claim still would fail.

A. Plaintiffs Fail to State an Unjust Enrichment Claim Under Kentucky Law.

Under Kentucky law, unjust enrichment requires privity of contract. *Kentucky v. Marathon Petroleum Co., LP*, CIV.A. No. 3:15-cv-354-DJH, 2016

WL 3199534, at *9 (W.D. Ky. June 8, 2016), a copy of which is attached as **Exhibit M**; *see also Mitchell v. Gen. Motors LLC*, No. 3:13-CV-498-CRS, 2014 WL 1319519, at *15 (W.D. Ky. Mar. 31, 2014) (unjust enrichment dismissed because customer purchased its vehicle from a dealership and not directly from GMC), a copy of which is attached as **Exhibit N**. As discussed above, no such privity exists here. Nowhere in the Complaint do Plaintiffs allege that they purchased EpiPen devices directly from Mylan, nor could they, as EpiPen devices require a prescription and are purchased through pharmacies. Therefore, Plaintiffs' claim for unjust enrichment should be dismissed under Kentucky law.

B. Plaintiffs Fail to State an Unjust Enrichment Claim Under Michigan, Connecticut, New Hampshire, or Kentucky Law.

The mere fact that Plaintiffs think Mylan's conduct was "unjust" does not give rise to an unjust enrichment claim. Plaintiffs must plead plausible allegations to show that they are entitled to relief, which they have not done.

Under Michigan law, in order to establish a claim for unjust enrichment, a plaintiff must plead and prove (1) the receipt of a benefit by the defendant from the plaintiff, and (2) that retention of the benefit is inequitable. *B & M Die Co. v. Ford Motor Co.*, 421 N.W.2d 620, 622 (Mich. App. 1988). Importantly, Michigan law is clear that where a plaintiff has been compensated for the benefit bestowed on the defendant, no cause of action for unjust enrichment will lie. *Hollowell v. Career Decisions, Inc.*, 298 N.W.2d 915 (Mich. App. 1980); *Kamalnath v. Mercy Mem'l Hosp. Corp.*, 487 N.W.2d 499 (Mich. App. 1992).

Similarly, under Connecticut law, a plaintiff seeking recovery for unjust enrichment must prove (1) that the defendants benefitted, (2) that the defendants unjustly did not pay the plaintiffs for the benefits received, and (3) that the failure of payment was to the plaintiffs' detriment. *Trenwick Am. Reinsurance Corp. v. W.R. Berkley Corp.*, 54 A.3d 209, 218 (Conn. App. 2012). As under Michigan law, where a plaintiff has received payment from the defendant for the benefit received by the defendant, no cause of action lies for unjust enrichment. *Id.*

Under New Hampshire law, "[a] plaintiff is entitled to restitution for unjust enrichment if the defendant received a benefit and it would be unconscionable for the defendant to retain that benefit. The party seeking restitution must establish not only unjust enrichment, but that the person sought to be charged had wrongfully secured a benefit or passively received one which it would be unconscionable to retain." *Gen. Insulation Co. v. Eckman Constr.*, 159 N.H. 601, 611, 992 A.2d 613, 620-21 (2010) (internal quotations and citations omitted). As under Michigan and Connecticut law, when a defendant has paid for the benefit it received, no cause of action lies for unjust enrichment. *See Axenic, Inc. v. Turner Const. Co.*, 63 A.3d 754, 766 (N.H. 2013).

The same principle exists under Kentucky law. *Helton v. Am. Gen. Life Ins. Co.*, No. 4:09-CV-118, 2010 WL 3516431, at *2 (W.D. Ky. Sept. 1, 2010) (dismissing unjust enrichment claim because defendants had paid for the value of the benefit they retained), a copy of which is attached as **Exhibit O**.

Here, Plaintiffs allege that Mylan obtained financial benefits from Plaintiffs, by way of Plaintiffs' payments for EpiPen devices. Compl. ¶¶ 88-89. However,

Plaintiffs fail to state a claim for unjust enrichment under Michigan, Connecticut, New Hampshire, or Kentucky law, because they received exactly what they paid for: EpiPen devices, sold in two-packs. Plaintiffs do not allege that they failed to receive the benefit for which they paid, or that they received anything less than what they expected. Quite the opposite: Plaintiffs (and/or their insurers or other third-party payors) each paid for two EpiPen devices, and they received two EpiPen devices, together with accompanying protection from potential harm and peace of mind. Plaintiffs' unjust enrichment count therefore fails to state a claim.

V. STATE-LAW CLAIMS BASED ON PRICING FOR EPIPEN DEVICES ARE PREEMPTED BY FEDERAL PATENT LAW.

To the extent that Plaintiffs are attempting to assert claims based on the prices that Mylan charged for a two-pack of EpiPen devices, *see, e.g.*, Compl. ¶¶ 34, 36, 55, 57, 88, that claim also would fail.

It is well established that state law must yield to congressional enactments when it "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Biotech. Indus. Org. v. Dist. of Columbia*, 496 F.3d 1362, 1372 (Fed. Cir. 2007) (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)). In the context at issue here, courts also have "long acknowledged the importance of the patent system in encouraging innovation. Indeed, the encouragement of investment-based risk is the fundamental purpose of the patent grant, and is based directly on the right to exclude." *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1383 (Fed. Cir. 2006) (internal quotations and citations omitted). As a result, the Federal Circuit has specifically recognized that Congress

is "the promulgator of patent policy," and that federal patent law reflects the results of Congress's deliberations regarding "the proper balance between innovators' profit and consumer access to medication." *Biotech*, 496 F.3d at 1373-74.

For this reason, courts have repeatedly held that state law claims challenging the pricing of a patented pharmaceutical product are preempted by federal patent law. The decision last year in *Southeastern Pennsylvania Transportation Authority v. Gilead Sciences, Inc.* ("*SEPTA*"), 102 F. Supp. 3d 688 (E.D. Pa. 2015), is instructive. There, the court held that certain state law claims brought against a pharmaceutical manufacturer for allegedly excessive drug pricing were preempted by federal patent law. *Id.* The *SEPTA* plaintiffs alleged that the defendant had violated California law by charging excessive prices for two patented drugs. *Id.* at 695-696. But the court held that the plaintiffs' claims were preempted by federal law to the extent they sought "to use state law to challenge Gilead's exercise of its exclusive patent rights to make pricing decisions." *Id.* at 703.

Likewise, in *Biotech*, the Federal Circuit determined that a District of Columbia statute regulating the cost of patented drugs was preempted by federal patent law. The court reasoned that the "underlying determination about the proper balance between innovators' profit and consumer access to medication . . . is exclusively one for Congress to make. . . . [W]here it is clear how the patent laws strike that balance in a particular circumstance, that is not a judgment the States may second-guess." 496 F.3d at 1374 (citing *Bonito Boats, Inc. v. Thunder Craft Boats Inc.*, 489 U.S. 141, 152 (1989)) (internal quotations omitted).

Here, the Complaint asserts that Mylan's decision to sell EpiPen devices in packs of two "was a thinly veiled mechanism for increasing their price" to "inflated" levels. Compl. ¶¶ 36, 55. While Plaintiffs' allegations largely focus on Mylan's decision to sell EpiPen devices in packs of two, Plaintiffs' real complaint is that they paid too much for those EpiPen devices, which Mylan has the exclusive right to market, distribute, and sell.[15] Essentially, Plaintiffs are asking the Court to mandate that Mylan sell EpiPen products at a lower price, just as the *SEPTA* plaintiffs sought to use state law to challenge the defendant's ability to set prices for its patented drugs. As in *SEPTA*, Plaintiffs cannot use state law to upset the balance regulated by the federal patent system. Therefore, to the extent that Plaintiffs' state-law claims are challenging Mylan's exercise of its exclusive patent rights to make pricing decisions, they conflict with – and are preempted by – federal patent law.

VI. IN THE ALTERNATIVE, THE COURT SHOULD STRIKE PLAINTIFFS' CLASS ALLEGATIONS.

For all the reasons above, the Court should dismiss Plaintiffs' Complaint in its entirety. If any of Plaintiffs' claims survive dismissal, however, the Court should, in the alternative, strike the Complaint's class allegations under Fed. R. Civ. P. 12(f).

[15] The fact that Mylan has licensed EpiPen products from Meridian is not relevant to this analysis. As the holder of patents on EpiPen devices, Meridian has the right to license its patent rights as it sees fit, and any attempt to use state law to challenge Mylan's pricing decisions affects the patent right.

"A court may strike class action allegations before a motion for class certification where the complaint itself demonstrates that the requirements for maintaining a class action cannot be met," *Pilgrim v. Universal Health Card, LLC*, 660 F.3d 943, 945 (6th Cir. 2011), and where discovery will not "alter[] the central defect in the class claim." *Id.* at 949. That is the situation here.

As a threshold matter, the Court should strike Plaintiffs' claims on behalf of a national class. Plaintiffs seek to bring their claims on behalf of a national class, as well as subclasses for purchasers in Michigan, Kentucky, Connecticut, and New Hampshire. Compl. ¶ 39. But a plaintiff can only state a claim under the consumer protection law of the state in which she resides or suffered injury. *Pilgrim*, 660 F.3d at 946. As a result, certification of the nationwide class that Plaintiffs allege would require the application of more than fifty different state consumer protection laws and legal standards. That alone is enough to warrant striking Plaintiffs' request for a national class. *See id.* at 946 (affirming dismissal of nationwide class on motion to strike because "different laws would govern class members' claims"); *id*. at 948-49 (citing numerous cases in which courts held that nationwide class certification would be inappropriate where plaintiffs sought to apply the laws of fifty states).

Plaintiffs' claims are also inherently unable to be certified as a class action. "Where many individual inquiries are necessary, a class action is not a superior form of adjudication." *Young v. Nationwide Mut. Ins. Co.*, 693 F.3d 532, 545 (6th Cir. 2012). Here, every state law on which Plaintiffs rely would require individual proof of causation. For example, the Michigan class is required to allege an injury

resulting from the alleged violation of the MCPA. *Mayhall*, 129 Mich. App. at 180, 183, 186. Connecticut law requires the causal element be shown by "[a]n actual cause that is a substantial factor in the resulting harm." *Stevenson Lumber*, 284 Conn. at 214 (citation omitted). New Hampshire requires the showing of a "causal link between the conduct at issue and his or her injury." *Mulligan*, 1998 WL 544431 at *11. And putative Kentucky class members must demonstrate a causal nexus between their loss and Mylan's allegedly deceitful conduct. *Corder*, 869 F. Supp. 2d at 838. By definition, causation depends on the specific circumstances of each putative class member, including whether or not they saw the Press Release, and when, why, and whether it caused them to purchase; whether they would have bought EpiPen products in single-packs, despite the health risks of doing so; and whether, and to what extent, they suffered any harm, given that insurance or other resources likely covered a large portion of the purchases by members of the putative class. These determinations bear directly on the fundamental issues of causation (and proving a causal link or nexus), and thus on the individualized proof required to prevail at trial and the ability of this Court to determine who is – and is not – a member of the putative class. *See In re Polyurethane Foam Antitrust Litig.*, 314 F.R.D. 226, 240 (N.D. Ohio 2014) ("Plaintiffs must instead show that the essential elements of their claims are capable of proof at trial through evidence that is common to the class rather than individual to its members.") (internal quotations, alteration, and citation omitted), a copy of which is attached as **Exhibit P**.

No amount of discovery could change the need to individually determine whether each plaintiff actually viewed the Press Release prior to their purchase of EpiPen devices and whether that caused them actual harm. Thus, even if Plaintiffs' individual claims were allowed to proceed (which they should not), this Court should strike the class allegations from the Complaint.[16]

CONCLUSION

For all these reasons, Defendant Mylan Specialty L.P. respectfully requests that this Court dismiss Plaintiffs' Complaint with prejudice or, in the alternative, strike the class allegations of the Complaint.

Respectfully submitted,

s/ Anthony A. Agosta

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[16] *See Lawrence*, 530 A.3d at 530 (individual determinations regarding who observed reports, negating injury/causation, would cause individual issues to predominate common ones); *Thornton v. State Farm Mut. Auto Ins. Co.*, No. 1:06-cv-00018, 2006 WL 3359482, at *4-5 (N.D. Ohio Nov. 17, 2006) (striking class allegations because claims would require individualized inquiry), a copy of which is attached as **Exhibit Q**; *Taylor v. CSX Transp., Inc.*, 264 F.R.D. 281, 296 (N.D. Ohio 2007) ("Certification is inappropriate where each plaintiff's claim will be highly individualized with respect to proximate causation") (internal quotations and citation omitted), a copy of which is attached as **Exhibit R**.

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* Motions for admission pending

Dated: November 22, 2016

CERTIFICATE OF SERVICE

I hereby certify that on November 22, 2016, I caused to be electronically filed the foregoing with the Clerk of Court using the CM/ECF system, which will then send a notification of such filing (NEF) to all counsel of record.

/s/ Anthony A. Agosta
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